

This document is scheduled to be published in the Federal Register on 02/01/2016 and available online at <a href="http://federalregister.gov/a/2016-01720">http://federalregister.gov/a/2016-01720</a>, and on FDsys.gov

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16CO]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to <a href="mailto:comb@cdc.gov">comb@cdc.gov</a>. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

## Proposed Project

Developing a Self-Management Tool for Individuals with Systemic Lupus Erythematosus - New - National Center for Chronic Disease Preventions and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Systemic Lupus Erythematosus (SLE) is an autoimmune disease in which the immune system produces antibodies to cells within the body leading to widespread inflammation and tissue damage.

SLE has a variety of clinical manifestations and can affect joints, skin, the brain, lungs, kidneys, and blood vessels.

Effective SLE management depends not only upon clinical interventions, but also on self-management— those things done on a day-to-day basis to manage SLE. SLE self-management requires gaining essential knowledge, skills, and confidence to manage the condition.

CDC previously launched a two-year project called 'Filling a Gap: Creating Educational Program, Tools, or Materials to Enhance Self-Management in Systemic Lupus Erythematosus' to identify and address the needs of lupus patients in practicing effective self-management. The purpose of this project is to develop a SLE self-management tool to improve the ability of people living with lupus to manage their condition.

The proposed information collection will assess a prototype CDC SLE self-management tool that is in development to ensure that the tool is usable and useful to members of the target audience. The tool is expected to be comprised of multiple SLE self-management resources that may include, but are not limited

to: Education resources about fatigue management, pain management, healthy diet, and exercise; symptom trackers; medication trackers; appointment calendars; resources about communication with family, friends, and co-workers about SLE; and strategies for coping with depression and anxiety.

CDC plans to make the tool available in an electronic format (web-based or a native mobile application) and will consider making it available as a printed resource, depending on the feedback obtained during the testing process.

The information collection will also gauge the needs of the target audience(s), tool format and delivery method(s), and the tool's clarity, relevance, salience and appeal. A series of focus groups with women with a diagnosis of SLE, and one-on-one telephone interviews with men with a diagnosis of SLE will be conducted to assess the tool. The same discussion guide will be used for all information collections.

The estimated burden per response for participating in a focus group discussion is two hours. The estimated burden per response for a discussion conducted via telephone interview is 45 minutes. Respondent burden also includes two hours for reviewing the prototype CDC SLE Self-management Tool in advance of the focus group meeting or telephone interview.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time.

The total estimated burden hours are 646.

## Estimated Annualized Burden Hours

Type of	Form Name	No. of	No. of	Avg.
Respondents		Respondents	Responses	Burden per
			per	Response
			Respondent	(in hrs.)
Women with SLE diagnosis	Screener for	192	1	10/60
	Women			
	Prototype CDC	128	1	2
	SLE Self-			
	management			
	Tool			
	Discussion	128	1	2
	Guide for Use			
	in Focus			
	Groups with			
	Women or			
	Interviews			
	with Men			10/60
Men with SLE	Screener for	40	1	10/60
	Men			
	Prototype CDC	20	2	2
diagnosis	SLE Self-			
	management			
	Tool			
	Discussion	20	1	45/60
	Guide for Use			
	in Focus			
	Groups with			
	Women or			
	Interviews			
	with Men			

Leroy A. Richardson, Chief, Information Collection Review Office, Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

[FR Doc. 2016-01720 Filed: 1/29/2016 8:45 am; Publication Date: 2/1/2016]